

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO WAVE 4 CASES ON ATTACHED EXHIBIT A	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF
DAUBERT MOTION TO PRECLUDE OR LIMIT OPINIONS OF
DEFENSE EXPERT JOHN R. WAGNER**

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Plaintiffs respectfully request that this Court exclude certain expert testimony proffered by Defendants Ethicon, Inc. and Johnson & Johnson's expert John R. Wagner, M.D. ("Dr. Wagner"). In support of their motion, Plaintiffs state as follows:

INTRODUCTION

Dr. John Wagner is an Obstetrician/Gynecologist with a subspecialty in Pelvic Floor Medicine and Reconstructive Surgery, and Plaintiffs do not challenge his qualifications as such.¹ Dr. Wagner's general reports set forth opinions on all liability issues with regard to the TVT, including failure to warn and design defect, to include opinions on the material properties of polypropylene mesh. However, Dr. Wagner has no experience drafting warnings or designing mesh devices. Dr. Wagner's experience in the field of Obstetrics and Gynecology does not render all of his opinions admissible. The admission of Dr. Wagner's unfounded opinions is both contrary to law and presents a serious risk of confusing the issues and misleading the jury.² As this Court previously noted, "[j]ust because an expert may be 'qualified . . . by knowledge, skill, experience, training or education' does not necessarily mean that the opinion that the expert offers is 'the product of reliable principles and methods' or that the expert 'has reliably applied the principles and methods to the facts of this case.'"³ Accordingly, Dr. Wagner should be prevented from offering testimony or opinions that exceed those permitted under *Daubert* and its progeny.

¹ See Wave 4 TVT General Expert Report of John R. Wagner, M.D. at p. 2 (attached as Ex. B); see also Curriculum Vitae of Dr. Wagner (attached as Ex. C).

² See *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) ("[T]he court must recognize that due to the difficulty of evaluating their testimony, expert witnesses have the potential to 'be both powerful and quite misleading.'") (citing *Daubert*, 509 U.S. at 596).

³ *Cisson v. C.R. Bard, Inc.*, MDL No. 2187, 2013 U.S. Dist. LEXIS 78061, *42-43 (S.D.W.V. 2013).

LEGAL STANDARD

For the sake of brevity and because the Court is fully aware of the legal standards governing the admissibility of expert testimony in the Fourth Circuit, Plaintiffs will not set forth a detailed discussion of the legal standard. It is known and understood that the admissibility of expert testimony is governed by the Federal Rules of Evidence, including but not limited to Rules 702, 403 and 104.⁴ The trial judge acts as a gatekeeper for scientific, technical, and other specialized knowledge.⁵

ARGUMENT

I. Dr. Wagner's General Opinions on Warnings Should Be Precluded or Limited

Dr. Wagner is unqualified to offer opinions on the adequacy of the Ethicon TVT Warnings to include the Instructions for Use ("IFU"). In fact, Dr. Wagner specifically testified that he has never held himself out to be an IFU expert.⁶ More specifically, Dr. Wagner has never designed an IFU, nor is he aware of the standards or criteria needed in drafting an IFU.⁷ Without any experience or knowledge of these standards, Dr. Wagner opines on the adequacy of the TVT IFUs generally, without reference to any specific iteration.⁸ However, Dr. Wagner specifically testified that the opinions he has offered with regard to the adequacy of Ethicon's TVT IFUs are based only on the 2015 TVT IFU.⁹ Thus, Dr. Wagner's opinions on any version of the TVT IFUs outside of the 2015 IFU are pure speculation, and the law is clear that such "unsupported

⁴ See *Bryte v. Am. Household, Inc.*, 429 F.3d 469, 476 (4th Cir. 2005) (federal law governs admissibility of expert testimony).

⁵ See *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 587 (1993); *Kumho Tire Co., Ltd., v. Carmichael*, 526 U.S. 137, 141 (1999).

⁶ See Wagner 3/13/2017 Dep. at 105:7-10 (attached as Ex. D).

⁷ *Id.* at 105:3-6, 105:11-17.

⁸ See Ex. B.

⁹ See Wagner 3/13/2017 Dep. at 196:12-17. See Wagner 3/13/2017 Dep. at Ex. 9 (attached as Ex. E).

speculation” is not only insufficient, but precisely what *Daubert* aims to prevent.¹⁰ Not only does Dr. Wagner possess inadequate experience, training, and knowledge with regard to designing IFUs, he only relied on the 2015 IFU in formulating his opinions. Therefore, Dr. Wagner’s opinions on the adequacy of Ethicon’s TVT warnings are unreliable and should be precluded. At a minimum, Dr. Wagner’s opinions on any TVT IFU outside of the 2015 version should be precluded.

II. Dr. Wagner’s General Opinions on the Design and Material Properties of the TVT Should Be Precluded or Limited.

Dr. Wagner does not have any experience in biomaterials engineering and has never designed mesh devices; however, he arbitrarily offers opinions regarding the design and the material properties of Ethicon’s TVT device.¹¹ Specifically, he opines that polypropylene does not undergo mechanical changes or degrade, and that the material properties of polypropylene do not have any clinical significance for patients.¹² Dr. Wagner simply does not have the requisite experience to proffer this opinion. Dr. Wagner’s opinions amount to nothing more than assumptions, and therefore are unreliable under *Daubert*.¹³

Dr. Wagner is a board certified Obstetrician/Gynecologist with a practice focused on female urology and pelvic floor medicine.¹⁴ Dr. Wagner does not have any specialized education, training, or applicable relevant experience specifically related to the design or

¹⁰ *Brown v. Auto-Owners Ins. Co.*, No. 96-2613, 1997 U.S. App. LEXIS 23559, *3(4th Cir., Sept. 8, 1997) (the expert's testimony must be grounded in the methods and procedures of science and not subjective belief or unsupported speculation); *see also Bryte v. Am. Household, Inc.*, 429 F.3d 469, 477 (4th Cir. 2005).

¹¹ *See* Ex. B.

¹² *See* Ex. B; Wagner 3/13/2017 Dep. at.163:4-164:23.

¹³ *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 587 (1993); *Brown v. Auto-Owners Ins. Co.*, No. 96-2613, 1997 U.S. App. LEXIS 23559, *3(4th Cir., Sept. 8, 1997) (the expert's testimony must be grounded in the methods and procedures of science and not subjective belief or unsupported speculation); *see also Bryte v. Am. Household, Inc.*, 429 F.3d 469, 477 (4th Cir. 2005).

¹⁴ *See* Ex. B at 2; Ex. C.

material properties of polypropylene mesh devices.¹⁵ In fact, Dr. Wagner testified that he does not hold himself out to be a biomedical engineer, pathologist, epidemiologist, or expert medical device design.¹⁶ More specifically, he has never conducted bench or laboratory research on polypropylene mesh.¹⁷ He has not examined or even ordered any particular analysis of the mesh he has explanted.¹⁸ He has never conducted any comparison studies between different mesh designs.¹⁹ And, he was even under the impression that the TVT mesh pore size is the same as that of the Gynemesh PS and Prolift mesh devices.²⁰ Furthermore, during Dr. Wagner's testimony, he clearly demonstrated that he is unaware of how the weight of pelvic mesh is measured or calculated.²¹ Essentially, Dr. Wagner has no knowledge of the scientific and material properties of the TVT mesh device. Despite this lack of knowledge, education, experience, and training about the design and material properties of polypropylene mesh devices, Dr. Wagner attempts to opine on TVT's design and material properties, including degradation, weight, porosity, and cut (laser or mechanical).²² These opinions undoubtedly exceed the bounds of his qualifications and should be precluded under *Daubert*.

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court exclude the above opinion testimony from John Wagner, regarding (a) the adequacy of the TVT warnings and (b) opinions regarding the design and scientific properties of the TVT mesh device. Plaintiffs further request all other relief to which they are entitled.

¹⁵ *Id.*; Wagner 3/13/2017 Dep. at 143:13-16, 143:21-22, 147:9-13, 148:12-15.

¹⁶ Wagner 3/13/2017 Dep. at 147:24-149:4 (Dr. Wagner testified that he is not an expert in the bench work of medical device design but claimed certain surgical experience).

¹⁷ *Id.* at 143:13-16.

¹⁸ *See Id.* at 147:9-13,

¹⁹ *Id.* at 143:21-22, 148:12-15.

²⁰ *Id.* at 196:18-198-10.

²¹ *See* Wagner 3/13/2017 Dep. at 65:17-67:8.

²² *See* Ex. B; Ex. C.

Respectfully submitted,

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Dated: April 13, 2017

CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on April 13, 2017, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

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